

**Notice of Allowability**

Application No.

10/092,357

Applicant(s)

BOIME ET AL.

Examiner

Art Unit

Lorraine Spector, Ph.D.

1647

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to election filed 4/25/2005.
2. ☒ The allowed claim(s) is/are 1-4, 6-11 and 13.
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 7/23/2002
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

Lorraine Spector, Ph.D.  
Primary Examiner  
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### **OBJECTION TO THE DRAWINGS**

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings submitted 05 March 2002 are obviously informal, and Figure 1 is not of sufficient quality (hand lettering and poor photocopying) to be published. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kate Murashige on 7/18/2005.

The application has been amended as follows:

**In claim 1:**

At the end of line two, insert --, and having a structure selected from the group consisting of--.

At line seven, after "variant thereof", insert --that binds to the corresponding glycoprotein hormone receptor--.

In the final line of the claim, prior to "subunits", insert --glycoprotein hormone--.

**Claims 5 and 12** have been cancelled.

**The allowed claims, 1-4, 6-11 and 13, have been renumbered** as 1-11, respectively.

**The Title of the Invention** has been amended to read: --MULTIFUNCTIONAL SINGLE CHAIN GLYCOPROTEIN HORMONES COMPRISING THREE OR MORE BETA SUBUNITS--.

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**In the specification:**

At page 2 line 5 (paragraph [05]), replace "U.S. Serial No. 08/933,693" with --U.S. Patent No. 6,693,074--.

At page 2 line 21 (paragraph [11]), replace "U.S. Serial No. 09/595,930" with --U.S. Patent No. 6,689,365--. (Note that application number in specification as filed should have been 09/565,930, correction requested by Kate Murashige).

**Reasons for Allowance**

The following is an examiner's statement of reasons for allowance:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

U.S. Patent No. 6,103,<sup>501</sup>~~051~~ discloses and claims glycoprotein hormone fusion proteins having two beta and one alpha subunits.

U.S. Patent No. 5,705,478 discloses and claims glycoprotein hormone fusion proteins having two beta subunits, with antagonist activity.

U.S. Patent No. 5,958,737 discloses and claims nucleic acids encoding glycoprotein hormone fusion proteins having two beta subunits.

U.S. Patent No. 6,225,449 discloses glycoprotein hormones with multiple CTP extensions.

U.S. Patent No. 6,242,580 discloses and claims single-chain glycoprotein hormone dimers.

U.S. Patent No. 6,635,256 is drawn to methods of using glycoprotein hormone fusion proteins having two beta and one alpha subunits.

U.S. Patent No. 6,689,365 is drawn to an FSH beta-LH beta-alpha pseudotrimeric fusion protein.

The art does not suggest higher order structures comprising three or more beta subunits. It is noted that the specification demonstrates that the species of claim 10 (renumbered as claim 9) binds all three glycoprotein hormone receptor molecules.

YML  
7/19/05

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

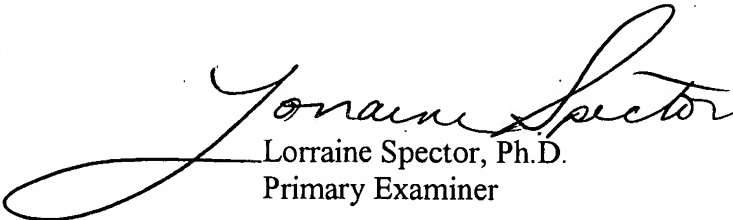
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to **571-273-8300**. Faxed draft or informal communications with the examiner should be directed to **571-273-0893**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Lorraine Spector, Ph.D.  
Primary Examiner